stryker®

Spine

Luxor™
Surgical Technique

- Minimally invasive procedures
- Luminated expandable oval retractor
- Complete visualization and optimal working space

LITe™
Less Invasive Technologies

Luxor™
Surgical Technique

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Acknowledgments

Stryker® Spine wishes to thank the global Luxor™ Surgeon Panel for their dedication to the development of the Luxor™ System.

Introduction

The objective of Stryker Spine Less Invasive Technologies (LITe™) is to replicate the clinical results of the corresponding open procedure. What sets the minimally invasive procedures apart from open procedures is that while delivering similar clinical results, these procedures offer reduced intraoperative blood loss*, reduced post operative mobilization times*, and the potential for minimized postoperative consumption of orally administered narcotics*.

The Luxor™ Retractor, part of the LITe™ platform, was designed to provide access to the thoracic and lumbar spine from a posterior approach via a small incision. The oval design of Luxor™ reduces the medial/lateral muscle retraction seen in some circular retractors, while providing more working space at the level of the incision.

Important

This Surgical Technique sets forth detailed, recommended procedures for using the Luxor™ System. It offers guidance that you should heed but, as with any such technical guide, each surgeon must consider the particular needs of each patient and make appropriate adjustments when necessary and as required.

Always refer to the package insert, product label and/or instructions before using any Stryker implant or instrument.

Note: No acid or alkaline solvents should be used in the cleaning of anodized components.

Note: Upon the completion of each surgical procedure, use adequate suction and irrigation to ensure the removal of any existing non-implantable materials.

Note: This is intended as a guide only. There are multiple techniques, and as with any surgical procedure, a surgeon should be thoroughly trained before proceeding.

*Data on file at Stryker Spine

Key Design Features

Radiolucent

- Complete visualization of anatomical landmarks

Silicon sleeve & Anatomical blades

- Prevent tissue from entering surgical site

Cobb-style initial dilator

- Facilitates tissue dissection while incorporating insertion safety

Large distal span

- Maximum access at surgical site

Oval design

- Maximizes working & visualization channels while minimizing tissue damage

Thin, shadowless lighting component

- Continuous panoramic lighting that conforms to surgical site

Reliance LITe™ Decompression Instruments

- Bayoneted
- Non-reflective coating
- Thinner shaft profiles
- Increased working shaft length

Fixation Instruments

- Accommodates Cannulated and Non-Cannulated screws
- Rod insertion
- Blocker insertion
- Construct adjustment and final tightening

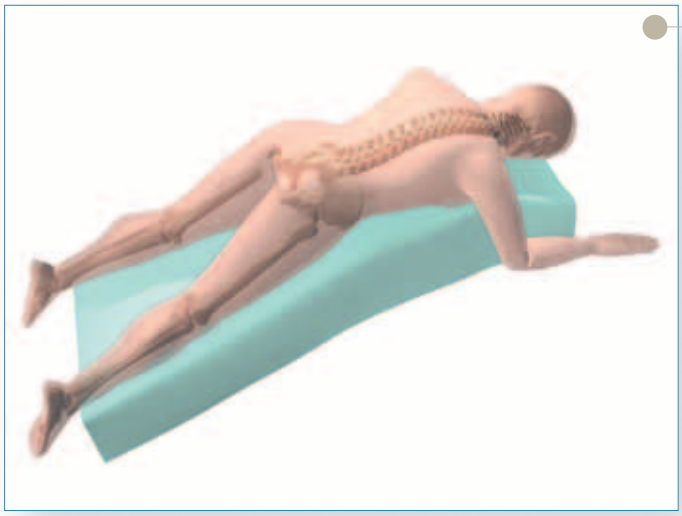


Figure 1

Patient Positioning

Luxor™ can be used successfully under local, epidural, spinal or general anesthesia. General anesthesia is commonly used since it is the most comfortable for the patient and allows immediate postoperative neurological assessment.

- The patient is prepped and draped in the usual sterile manner for posterolateral fusion with pedicle screw fixation.

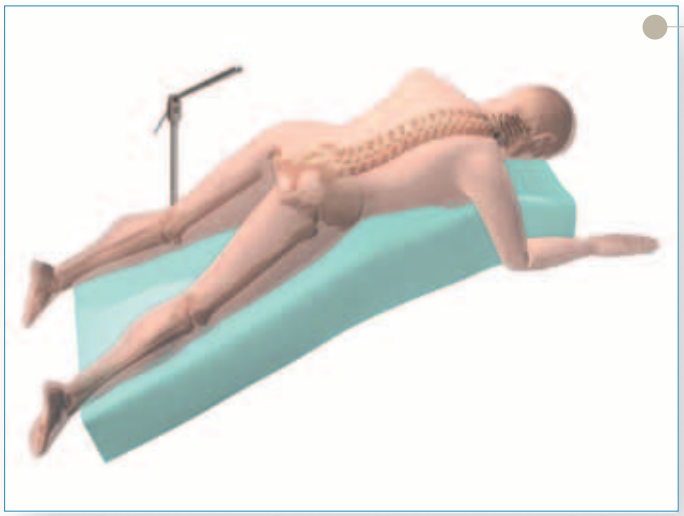


Figure 2

Arm Assembly Positioning

The **Mediflex Flex Arm Post (48250240)** mounts to the hospital bed rail. Check compatibility of the **Mediflex Flex Arm Post** to the hospital bed prior to surgery.

- Mount the **Arm Post** to the bed rail on the opposite side of the surgeon near the patient's hip.
- Turn the **Arm Post** locking mechanism clockwise to secure it to the bed.

Figure 3

- Once the **Arm Post** is secure, attach the **Snake Arm (48250230)** to the **Arm Post** and lock into place.
- The **Snake Arm** should be positioned to lie across the patient and wrap in front of the surgeon.

Note: For additional information, see the Mediflex Flex Arms™ Surgical User's Manual.

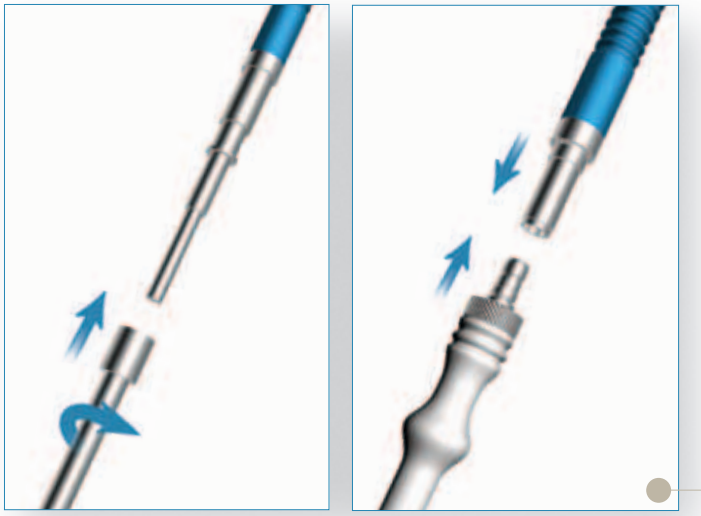


Figure 4

Lighting Preparation

- Determine the type of light source available in the OR.
- Choose the corresponding Luxor™ **Lightsource Adapter**:
  - **Stryker / ACMI / Zimmer Lightsource Adapter** (233-050-071)
  - **Storz Lightsource Adapter** (233-050-073)
  - **Olympus Lightsource Adapter** (233-050-072)
  - **Wolf / Dyonics Lightsource Adapter** (233-050-074)
- Attach the **Universal Light Cable** (**48250215**) to the appropriate Adapter and insert into the light source.
- Attach the other end of the **Universal Light Cable** to the **Lighting Component** (**48250210**).
- Turn on the light source power to verify light output.

Note: the Universal Light Cable is made of clear fiber optics. This is designed to easily identify broken fibers. If light output is low this instrument may need to be replaced.

Note: The Lighting Component is a single use instrument.

Instrument Bar

48250240
Arm Post

48250230
Snake Arm

48250215
Universal Light Cable

48250210
Lighting Component

233-050-071 - Stryker/ACMI/Zimmer
233-050-073 - Storz
233-050-072 - Olympus
233-050-074 - Wolf/Dyonics
Lightsource Adapters

Establishing Access

A/P images are used to confirm placement of the Luxor™ System.

The Retractor Base is delivered via a dilation system at approximately the same angle as the pedicle screws are to be inserted.

Upon insertion, the Luxor™ retractor exposes portions of the lamina, facet joints, and transverse process.

The following steps are taken to assure the correct positioning of the Luxor™ System.

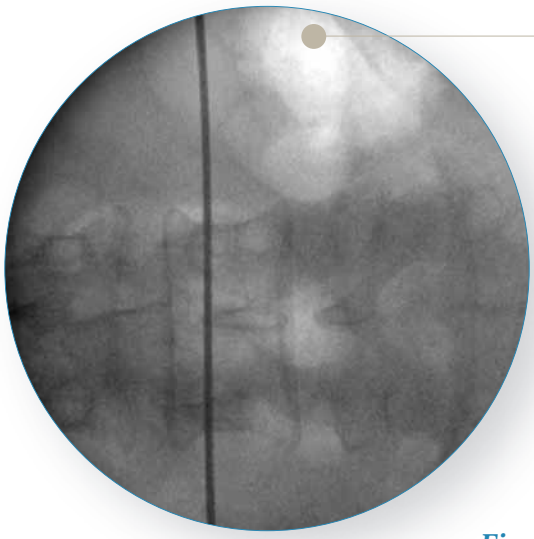


Figure 5

Markings

- Using A/P imaging, place the **Guide Pin (48250010)** transversely across the mid-line of the cephalad pedicles.
- Draw a line extending several inches lateral to the pedicles.

48250010
Guide Pin

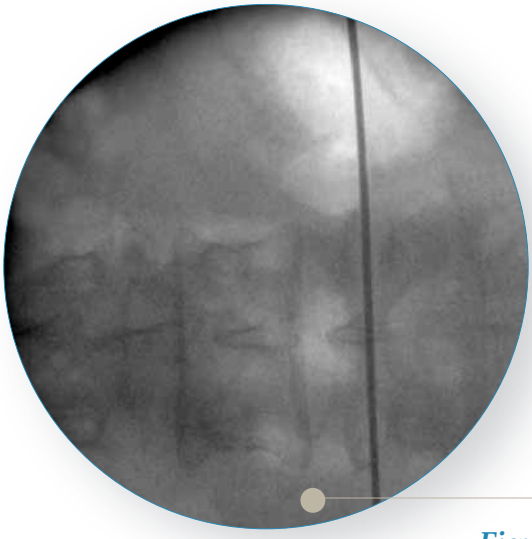


Figure 6

▶ Repeat for the caudal pedicles.

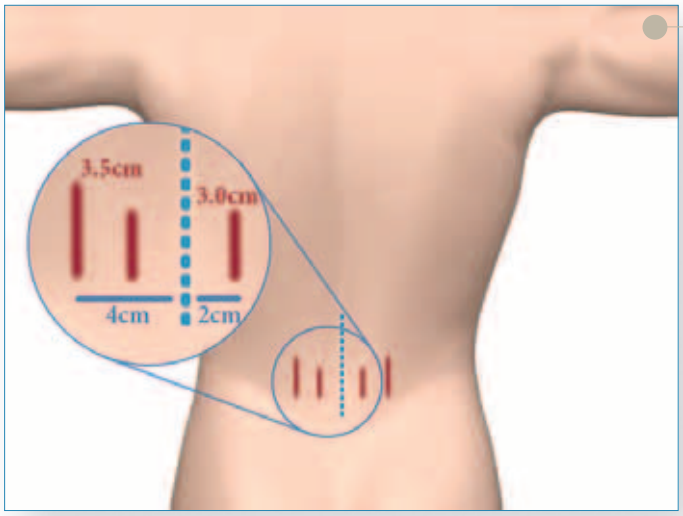


Figure 7

Carefully determine the appropriate entry point and trajectory for the Luxor™.

- For decompression, the entry point is approximately 2cm off mid-line with a more medial trajectory.
- For pedicle screws, the entry point is approximately 4cm off mid-line with a more lateral trajectory.

Note: The entry point is typically at or cephalad to the accessory process (AP) on the transverse process.

- A 3.5cm incision parallel to the spine is made at the puncture site.
- Incise the fascia to make tissue dilation easier.

Note: For procedures not requiring distal expansion of the retractor, a 3.0cm incision can be used for insertion.

Note: If tissue dilation is difficult increase the fascial incision.

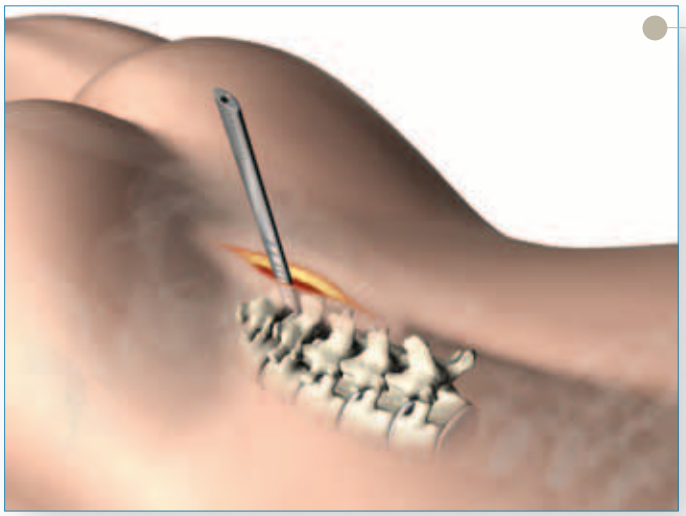


Figure 8

Initial Dilator Insertion

- Place the cobb style **Initial Dilator (48250011)** through the incision.
- Advance the Dilator through the tissue while directing it toward the inferior aspect of the superior lamina under lateral imaging.
- The **Dilator** is advanced through the lumbodorsal fascia.
- Location of the cobb style **Initial Dilator** is confirmed using imaging.
- Note the depth marking of the **Dilator** in relation to the skin.

The Dilators have depth markings (40, 50, 60, 70, 80, 90, 105, 120mm) laser etched which correlate to retractor blade lengths.

- Choose a **Retractor Blade** length **(48250(040)-(120))** based on where the top of the skin meets the Dilator.

Note: If the skin is between two markings on the Dilator choose the next longest Blade.

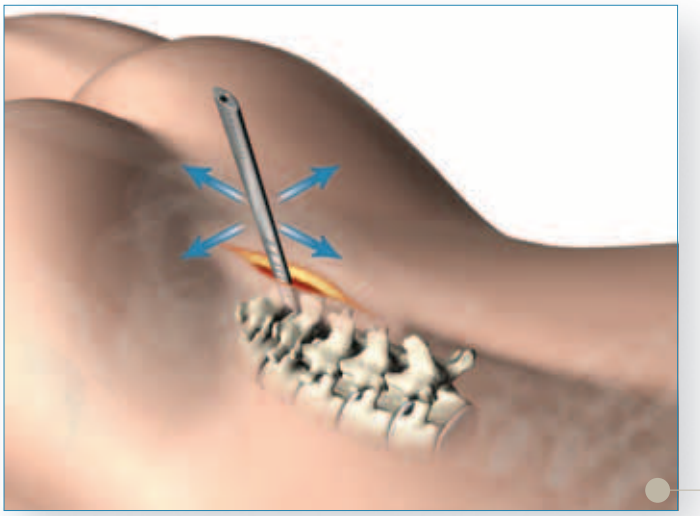


Figure 9

- Use the cobb style **Initial Dilator** to palpate the lamina in both the sagittal and transverse planes. This confirms an appropriate approach laterally.
- The tip of the **Dilator** is used to sweep the paraspinal musculature off the laminar edge.

Note: The Dilator (22mm width) is designed not to enter the intralaminar space when oriented cephalo-caudal.

Note: By keeping the Dilator tip in the subperiosteal space, the dissection is essentially bloodless.

Note: Feel, fluoroscopy, anatomical knowledge, review of preoperative images, and partial visualization may all contribute towards desired instrument placement accuracy.

Note: Great care must be taken to avoid penetration of the ligamentum flavum and inadvertent dural puncture with possible nerve injury or spinal fluid leak.

Note: If using the Guide Pin do not direct it lateral to the lamina or facet, which risks injury to the nerve root or deeper structures.

Note: To ensure that the Guide Pin was not bent during a prior surgical procedure, pass the Guide Pin through the cannulation in the cobb style Initial Dilator. This activity confirms that the Guide Pin is not bent, and reduces the risk of the Guide Pin being advanced forward into the canal space when used through the cobb style Initial Dilator during the dilation process.

48250011
Cobb Style Initial Dilator

48250040 - 40mm
48250050 - 50mm
48250060 - 60mm
48250070 - 70mm
48250080 - 80mm
48250090 - 90mm
48250105 - 105mm
48250120 - 120mm
Retractor Blades

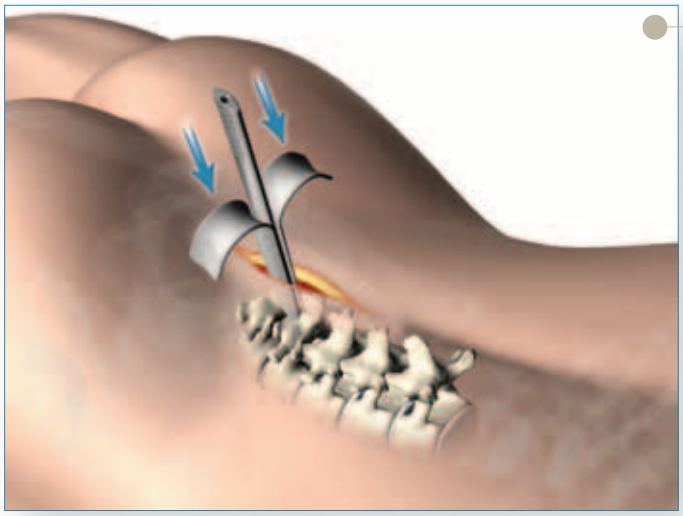


Figure 10

Subsequent Dilator Insertion

- Slide the **Kelly Retractors (48250017)** around the cobb style **Initial Dilator** and into the incision.

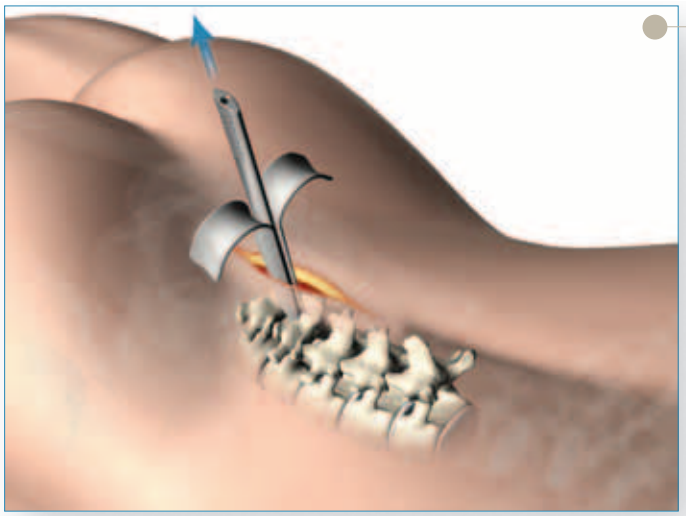


Figure 11

- Remove the cobb style Initial Dilator.

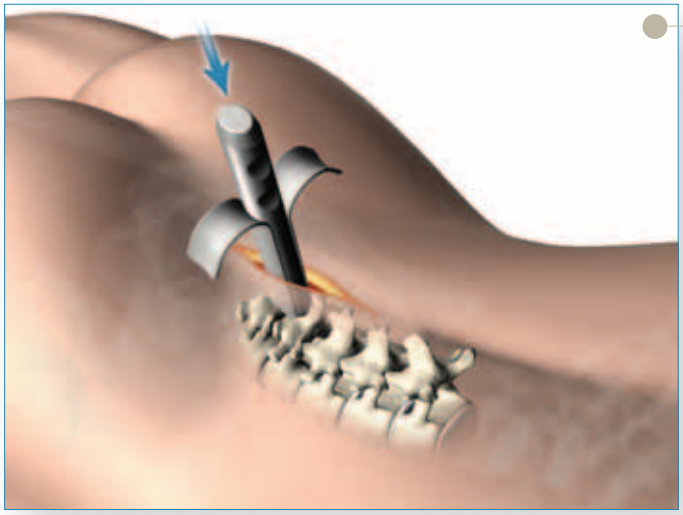


Figure 12

- Insert the **Blunt Dissector (48250018)**.
- Remove the **Kelly Retractors**.
- Use the Blunt Dissector to penetrate and gently spread and dissect soft tissue down to the lamina.
- Use imaging to confirm the placement of the Blunt Dissector on the superior facet.

Note: The **Blunt Dissector** may be used to probe and identify the anatomy.

Note: If additional assistance is needed introducing the **Blunt Dissector**, use both the **Kelly Retractors (48250017)** together to facilitate introduction.

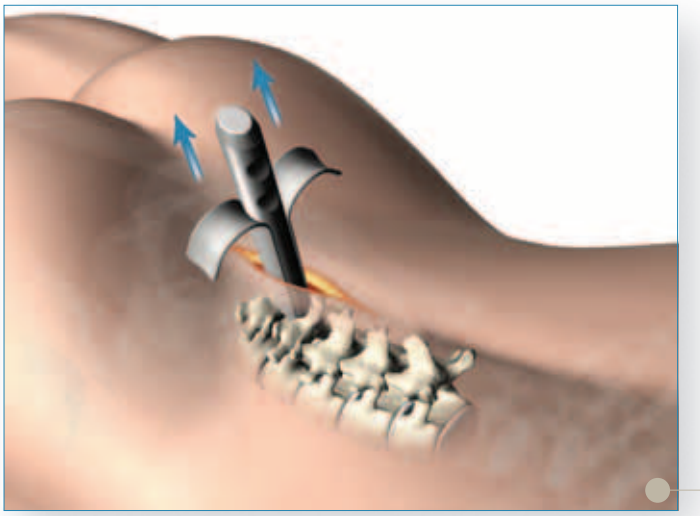


Figure 13

Figure 14

Retractor Assembly

Assemble each **Retractor Blade** into the **Retractor Base** (**48250020**)

1. Orient the **Retractor Base** so that the variable driving screw and post are pointing up.
2. Align the hole in the proximal end of the **Retractor Blade** with the pin in the **Retractor Base**.
3. Lightly squeeze the **Retractor Blade** on the proximal edges and insert the **Retractor Blade** into the **Retractor Base**.

48250017
Kelly Retractors

48250018
Blunt Dissector

48250020
Retractor Base

48250040 - 40mm
48250050 - 50mm
48250060 - 60mm
48250070 - 70mm
48250080 - 80mm
48250090 - 90mm
48250105 - 105mm
48250120 - 120mm
Retractor Blades

Figure 15

4. Release the **Retractor Blade** so that it engages the **Base**.
5. The cutouts at the top of the **Blade** should snap into the rectangular features in the **Base**.
6. Repeat the process for the second **Blade**.

Note: If a side of the **Retractor Blade** does not engage the **Retractor Base**, push on the 1mm edge of the **Blade** that is not engaged toward the cephalo-caudal orientation of the Base.

Note: The **Blades and Base** are color coded. Match the appropriate **Blade** color with the corresponding **Base** color during assembly.

Figure 16

- Based on the Blade length, obtain the corresponding **Silicon Sleeve (48251(040)-(120)**.
- With the **Retractor** in the closed state, dip the **Retractor Blades** in a saline bath.
- Slowly slide the corresponding **Silicon Sleeve** onto the **Retractor Blades** until it contacts the **Retractor Base**.

Note: The **Silicon Sleeve** is a single use instrument.

Note: The **Silicon Sleeve** should be slightly longer than the longest **Retractor Blade** being used.

Figure 17

Note: In cases where the **Retractor** cannot be actuated due to docking on bone, using **Blades** of different length is recommended.

Note: The **Silicon Sleeve** may need to be cut or altered to accommodate the varying blade lengths chosen.

Note: The sterile **Sleeve** should be cut with a sterile cutting instrument prior to assembly onto the **Retractor** .

Note: No jagged edges or visible silicon fragments should be present on the Sleeve when introducing the **Retractor** assembly into the incision.

Figure 18

- Insert the **Lighting Component** into the **Retractor Base**. The **Lighting Component** should be inserted between the **Retractor Blade** and **Silicon Sleeve**.
- The **Lighting Component** is inserted until the black bar on the Component is even with the Retractor Base.
- The **Lighting Component** should be oriented so that the "Stryker LITe™" logo is facing up.

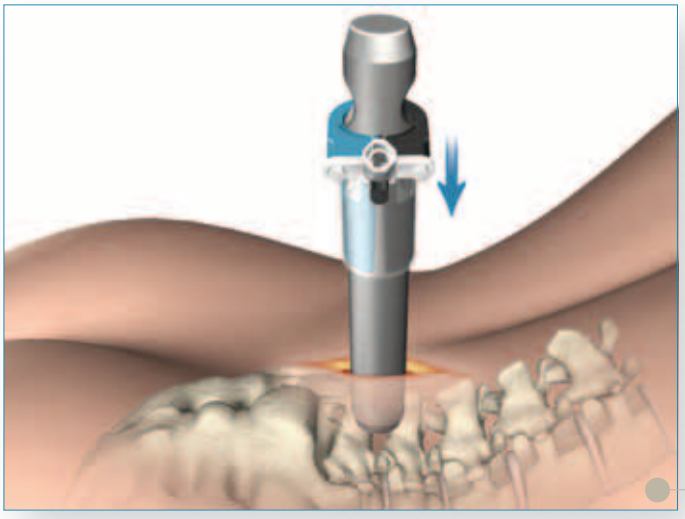


Figure 19

Retractor Insertion

- Slide the closed **Retractor** assembly over the **Blunt Dissector** with the variable drive screw and post positioned laterally.
- Dock the **Retractor** on the lamina.

Instrument Bar

48251040 - 40mm
48251050 - 50mm
48251060 - 60mm
48251070 - 70mm
48251080 - 80mm
48251090 - 90mm
48251105 - 105mm
48251120 - 120mm
Silicone Sleeve

48250210
Lighting Component

48250020
Retractor Base

48250018
Blunt Dissector

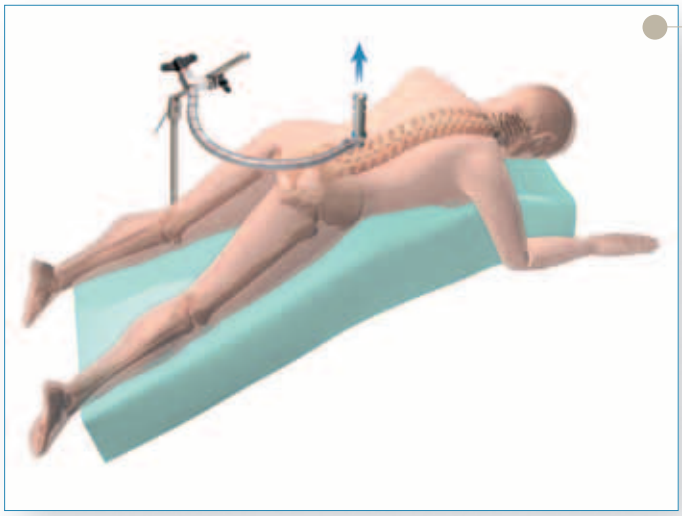


Figure 20

- Attach the **Snake Arm** to the **Retractor Base**.
- Lock the **Snake Arm** to the **Retractor Base** post by turning the collet.
- Secure the **Arm Assembly** by tightening the knobs.
- Remove the **Blunt Dissector**. This establishes an oval operative corridor to the lamina and interlaminar space.
- Use imaging to confirm appropriate positioning.

Note: If repositioning of the Retractor is necessary to expose the laminar edge, use the **Driver (48250200)** to collapse the Retractor. The Retractor can then be moved or angled over the pathology using the cobb style Initial Dilator. Once in the proper location, the Arm Assembly is tightened.

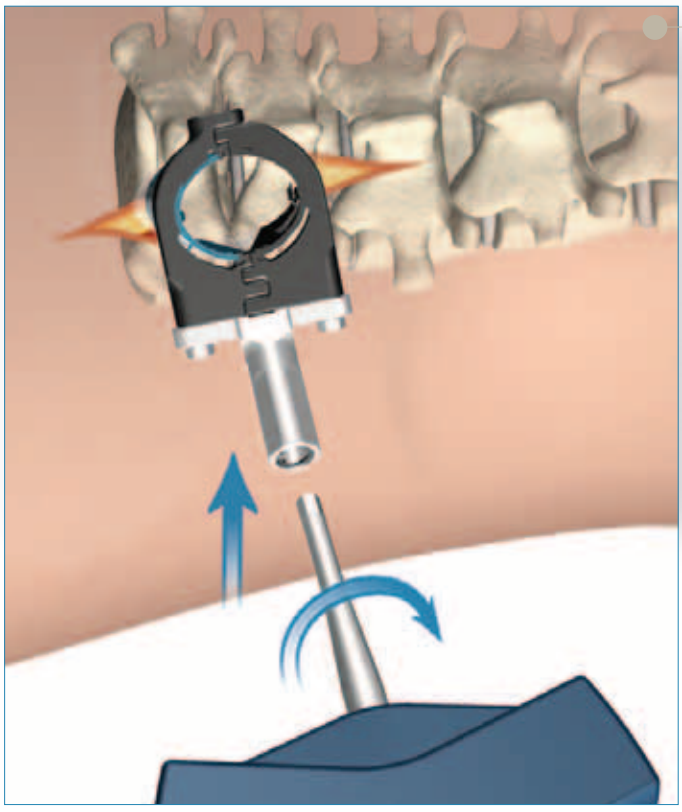


Figure 21

Retractor Variable Opening/Closing Mechanism

- Insert the **Driver (48250200)** into the post of the **Retractor Base** and screw down (clockwise) the variable drive screw to expand the distal end of the Retractor Blades.
- If necessary, gently rock the **Retractor Base** in the cephalo-caudal direction during expansion.

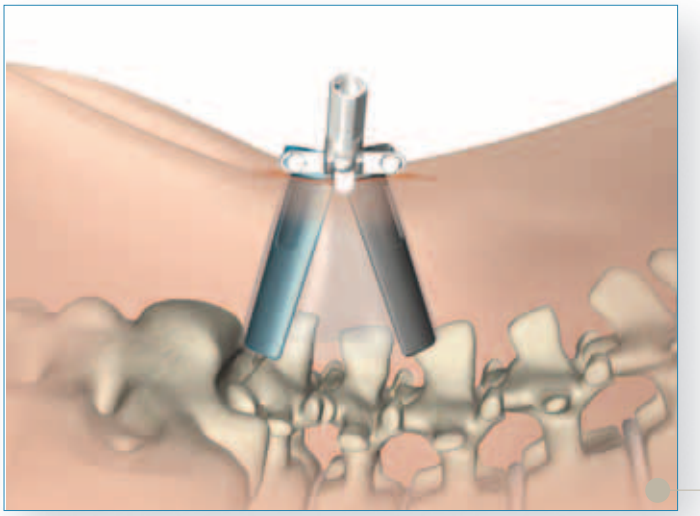


Figure 22

- Confirm expansion and position of the Luxor™ System with imaging.

Note: Distal opening of the Retractor is dependant on the Blade length. There is a mechanical stop in the Retractor base with a maximum opening of 22.5 degrees. This correlates to:

Blade Length (mm)	Retractor Distal Span with Silicon (mm)	Maximum Rod Length (mm)
40	58	55
50	63	60
60	68	65
70	75	70
80	79	75
90	82	80
105	80	80
120	78	75

Instrument Bar

48250230
Snake Arm

48250020
Retractor Base

48250018
Blunt Dissector

48250200
Driver

Disc Preparation and Removal

Luxor™ System offers a comprehensive set of Reliance™ LITe™ decompression instruments. This Reliance™ LITe™ set consists of:

- Penfield Elevators: Inspection of the surgical site between dura and bone.
- Nerve Hooks: Retract nerve during surgical procedure. Blunt tip to help protect nerve.
- Nerve Retractors: Retract compressed nerve root away from disc space.
- Nerve Probes: Inspection of the surgical site. The ball tip helps to prevent damage of the nerve.
- Woodson Probes: Exploration of the disc space.
- Suction Tips: Provide suction capabilities to evacuate fluid and debris from surgical site.
- Kerrison Rongeurs: Remove disc material, cartilage and hard connective tissue.
- Sypert Rongeur: Remove hard connective tissue. Instrument designed exclusively for use through the Luxor™ Retractor.
- Bovie: Dissect soft tissue.
- Bi-Polar: Dissect soft tissue.

Penfield Bayoneted

Sypert Rongeur

Nerve Hook Bayoneted,

Woodson Probe Bayoneted

These instruments are designed with:

- Bayoneted working shafts provide greater visibility while working through the Retractor.
- Working lengths of the 16cm or more for surgical procedures in the lower posterior thoracic and lumbar spine.
- Non-reflective coating to further increase visibility by reducing glare, while working through the Retractor.
- Handle profiles and shaft diameters minimized to provide greater visibility.
- Tips rounded for safety.

Ball Probe Bayoneted

Nerve Root Retractor

Suction Tip with Bend

Micro Scissor

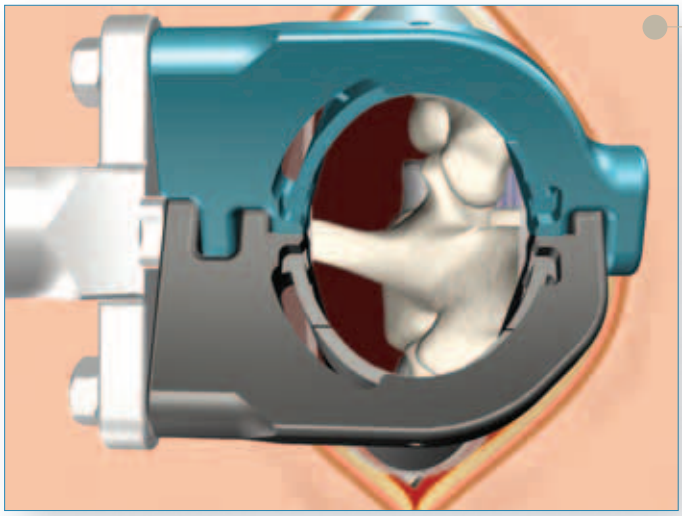


Figure 23

Disc Preparation and Removal Continued

- Identify the offending disc material.
- Enter the disc space at the vertebral margins.
- Resect the posterior lip of the vertebral body. This will simultaneously help free the cartilagenous endplate and provide direct entry to the disc space.

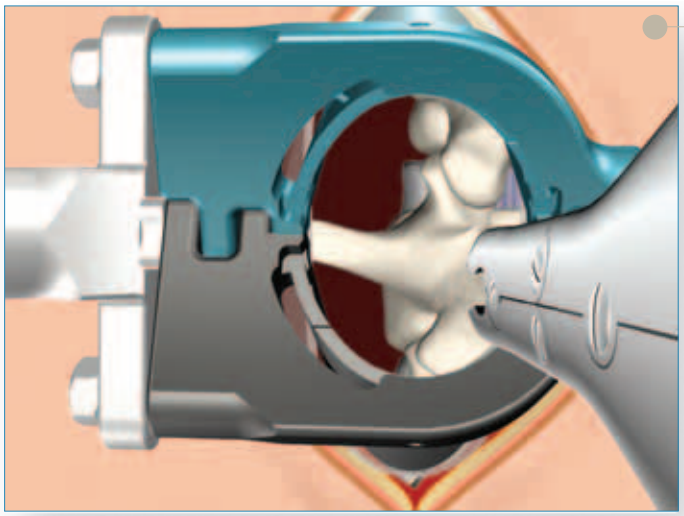


Figure 24

- Remove the offending disc material with a **Sypert Rongeur (48247001)**.
- Intradiscal and extradiscal work can be executed, as one would normally perform during a microdiscectomy.

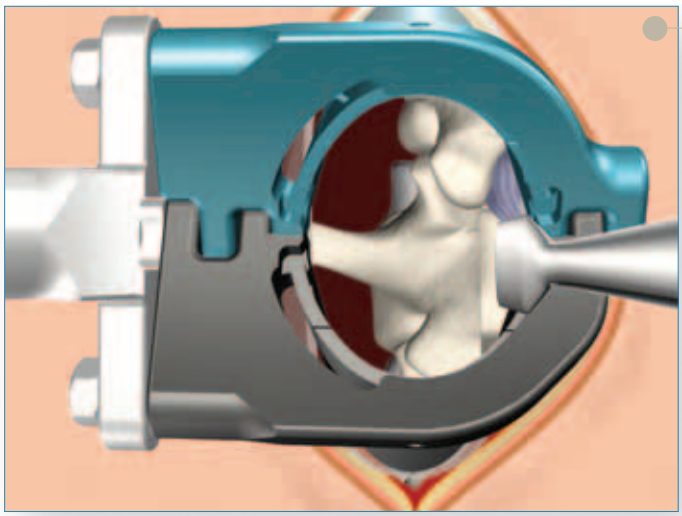


Figure 25

- The nerve root and spinal canal are explored to ensure the decompression is complete.
- Once the nerve root is decompressed, irrigate the disc space thoroughly.

Figure 26

Interbody Fusion

A shaver (TPS Saber; Stryker Endoscopy) is ideal to free the cartilagenous endplates while preserving the bony endplate.

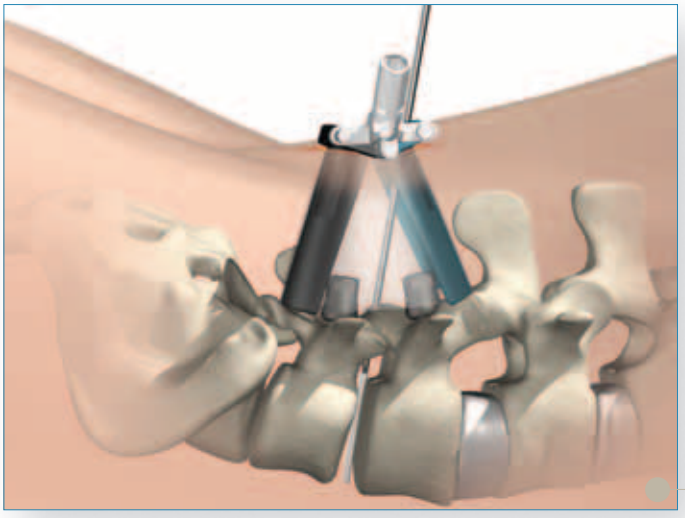


Figure 27

If an Interbody Fusion is to be performed, complete the discectomy, leaving the anterior and lateral aspects of the annulus intact.

▶ Prepare the endplate for the interbody fusion.

Instrument Bar

48247001
Sypert Ronguer

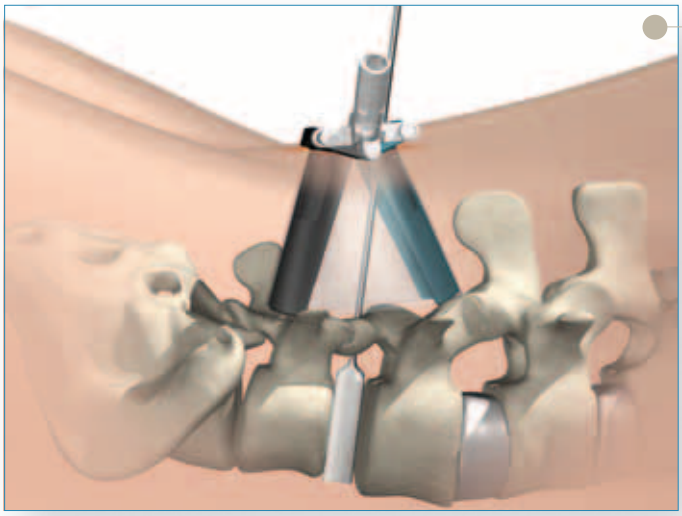


Figure 28

Graft Insertion

- Once the disc space is meticulously prepared, insert cancellous bone into the disc space using angled and straight forceps.

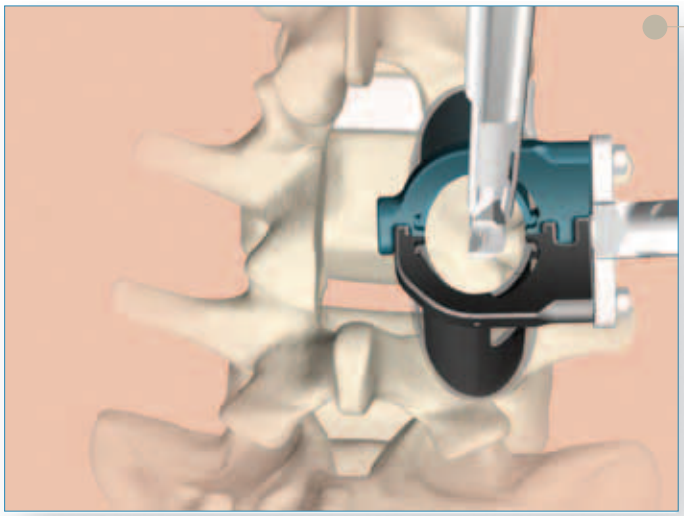


Figure 29

- Subsequently, use available bone tamps to impact the cancellous bone. The anterior longitudinal ligament and remaining annulus will contain the graft.

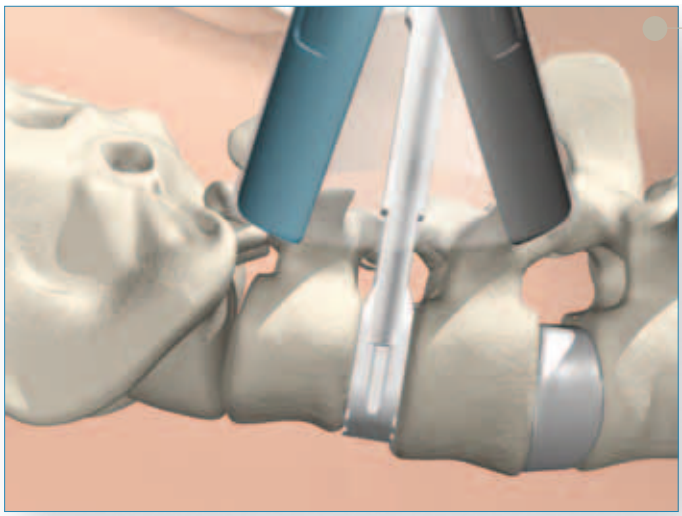


Figure 30

- Insert the allograft. Carefully use an angled osteotome or bone tamp to slide the allograft. The chamfered edge facilitates this maneuver.
- Pack additional cancellous bone medial to the first graft, then insert the second graft.
- To achieve a posterolateral fusion, decorticate the facet, pars, transverse processes and sacral ala using a burr, chisels, curettes, kerrisons, and/or rongeurs in the normal manner.
- Place the bone graft over the decorticated bone in the usual manner.

Screw Insertion: Cannulated

The Luxor™ System is used in conjunction with Stryker Spine systems (i.e., Xia Precision System, Techtonix™). See the appropriate Surgical Technique for additional information and device package insert for indications, contraindications, warnings & precautions.

Figure 31

- Insert the **Jam Shidi 48237 (105), (110), (115), (135)** through the **Luxor™ Retractor** to the intersection of the facet and transverse process.
- Confirm that the appropriate pedicle starting place has been determined using both A/P and lateral images.

Instrument Bar

10 Gauge, 9 inch	**48237110**
10 Gauge, 5 inch	**48237105**
11 Gauge, 5 inch	**48237115**
13 Gauge, 5 inch	**48237135**

Jam Shidi

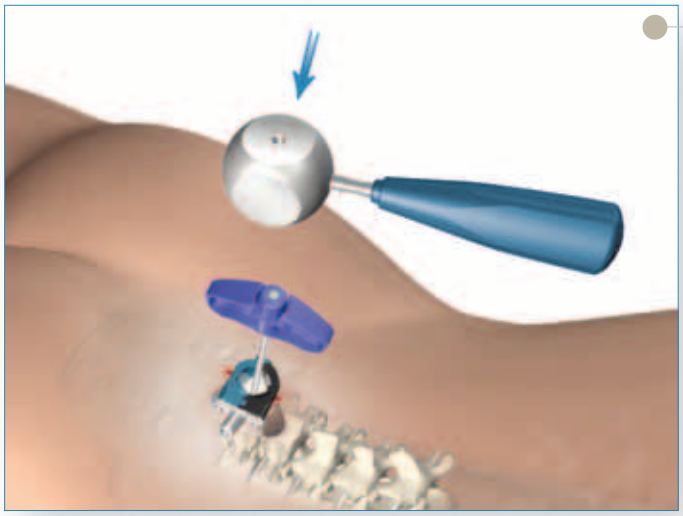


Figure 32

Use the **Jam Shidi** needle to gain access to the pedicle.

- After placing the **Jam Shidi** at the intersection of the facet and the transverse process, the needle may be advanced partially through the pedicle using the **Slap Hammer (48237120)**.

Figures 33A & 33B

- As the pedicle is navigated with the **Jam Shidi**, it should approach the medial wall of the pedicle on the A/P view and should approach the base of the pedicle on the lateral view.

Figures 34A & 34B

- When the needle reaches the medial wall on the A/P view, verification needs to be performed in the lateral view to ensure the needle is past the base of the pedicle.

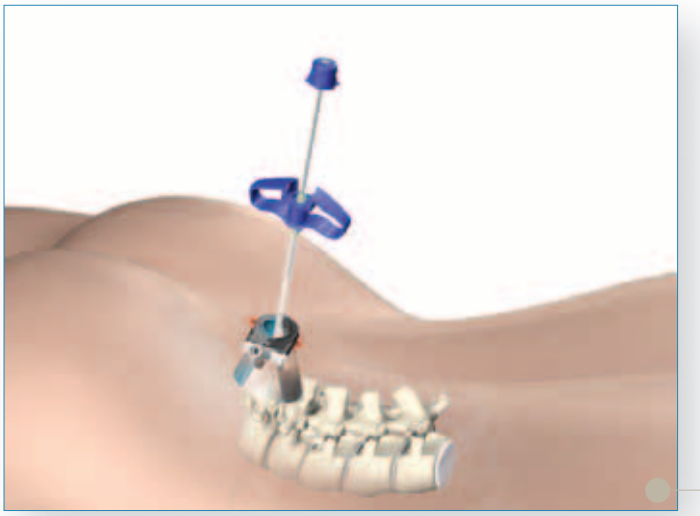


Figure 35

▶ Remove the inner trocar of the **Jam Shidi**.

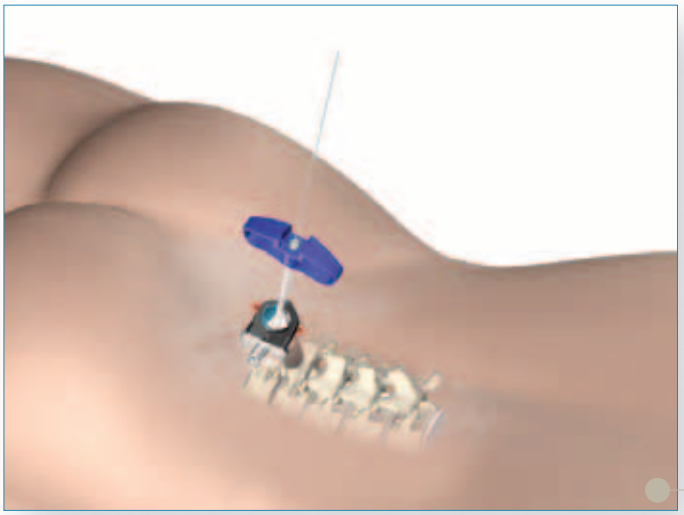


Figure 36

▶ The removal of the **Jam Shidi** inner trocar allows the **K-Wire** (**Sharp - 48230230, Blunt - 48230231**) to be inserted into the pedicle.

▶ Caution should be practiced with regards to the position of the **K-Wire** in order to avoid the advancement of the **K-Wire**.

Note: The **K-Wire** is 1.2mm in diameter.

Note: The **K-Wire** is a single use instrument.

Instrument Bar

10 Gauge, 9 inch 48237110
10 Gauge, 5 inch 48237105
11 Gauge, 5 inch 48237115
13 Gauge, 5 inch 48237135

Jam Shidi

48237120

Slap Hammer

Sharp 48230230
Blunt 48230231

K-Wire

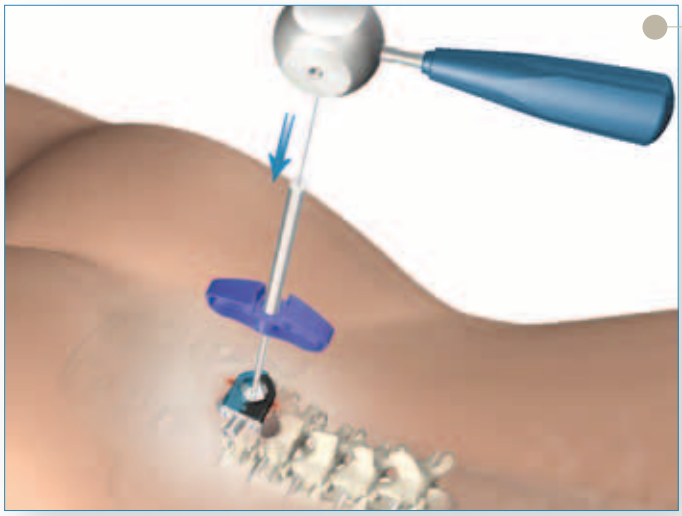


Figure 37

Use the **K-Wire Guide Tube** (**48230235**) to prevent the **K-Wire** from bending or moving during insertion.

- Place the **K-Wire Guide Tube** over the **K-Wire** and dock on the **Jam Shidi**.
- Use the **Slap Hammer** to impact the **K-Wire**.

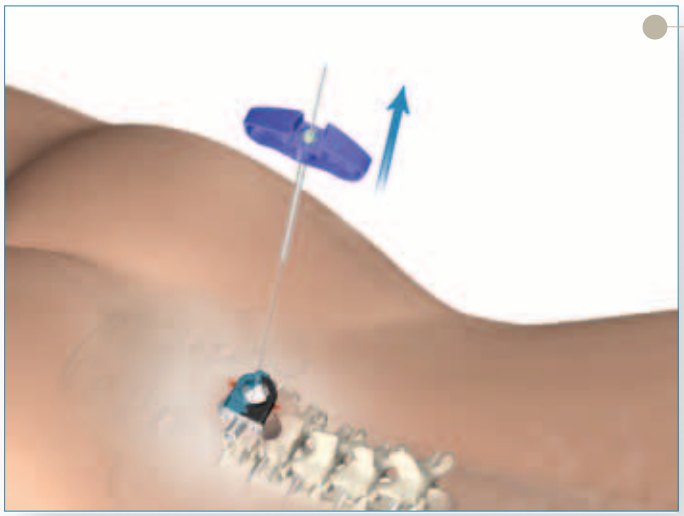


Figure 38

- Once the **K-Wire** is inserted, remove the outer shaft of **Jam Shidi**.
- Hold the **K-Wire** in position when removing the **Jam Shidi**.

Figure 39

- Prepare the pedicle by placing the **Xia® Precision Square Awl** (**48237001**) over the **K-Wire** and twisting into the pedicle.
- Hold the **K-Wire** in position when removing the **Awl**.
- Use the cannulation of the **Slap Hammer** to impact the **Awl**.

Note: The Awl has a stop at 12.0mm.

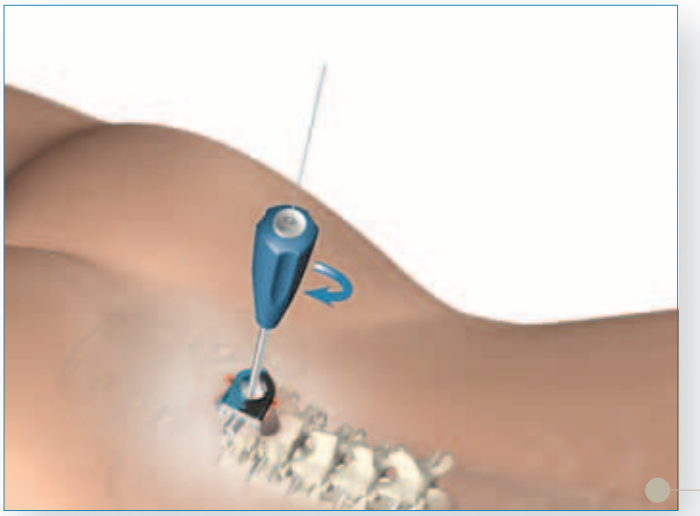


Figure 40

- If the bone is too hard, the appropriate Tap may be used to prepare the pedicle screw canal.
- The **Xia® Precision Taps** (**5.5mm – 48230165, 6.5mm – 48230166, 7.5mm – 48230167**) are calibrated and laser etched with 10.0mm intervals to help indicate the depth at which the **Tap** has been inserted as well as to help determine proper screw length.

Note: The length of the Taps' thread is 25mm.

Instrument Bar

Sharp 48230230
Blunt 48230231
K-Wire

48230235
K-Wire Guide Tube

48237120
Slap Hammer

48237001
Xia® Precision Square Awl

5.5mm 48230165
6.5mm 48230166
7.5mm 48230167
Xia® Precision Taps

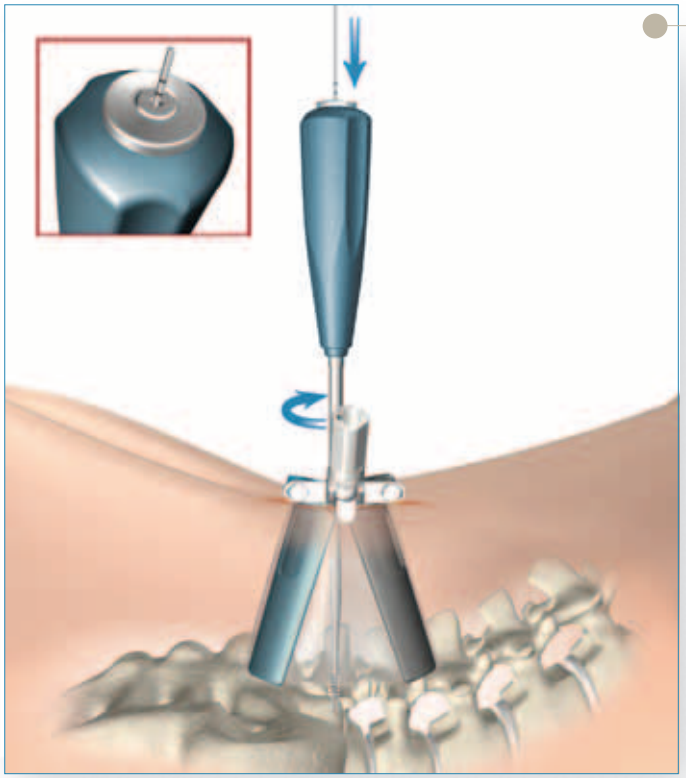


Figure 41

Note: 1.0cm interval markings on the **K-Wire** provide the cannulated instruments depth in the pedicle.

- As an instrument advances into the pedicle, the proximal end of the instrument will move relative to the markings. If this does not occur during insertion the procedure should be stopped and fluoroscopy should be used to verify the position of the **K-Wire** in relation to the **Precision Square Awl** or **Precision Tap**.

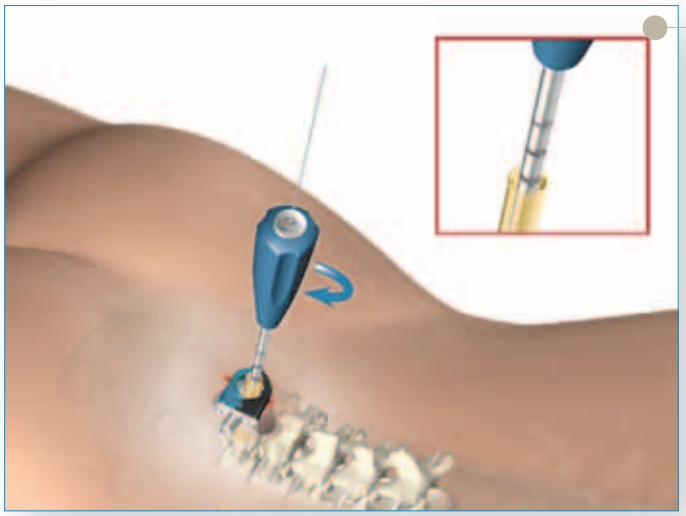


Figure 42

- The **Tap Sleeve (48231315)** can be used to prevent soft tissue from contacting the **Taps'** thread.

- Check pedicle depth with either fluoroscopy or read the depth from the **Tap Sleeve** as it moves along the proximal shaft of the **Taps**. There are markings at 30, 40 and 50mm.

Note: The **Tap Sleeve** is made of radiolucent Ultem Poly Ether Imide.

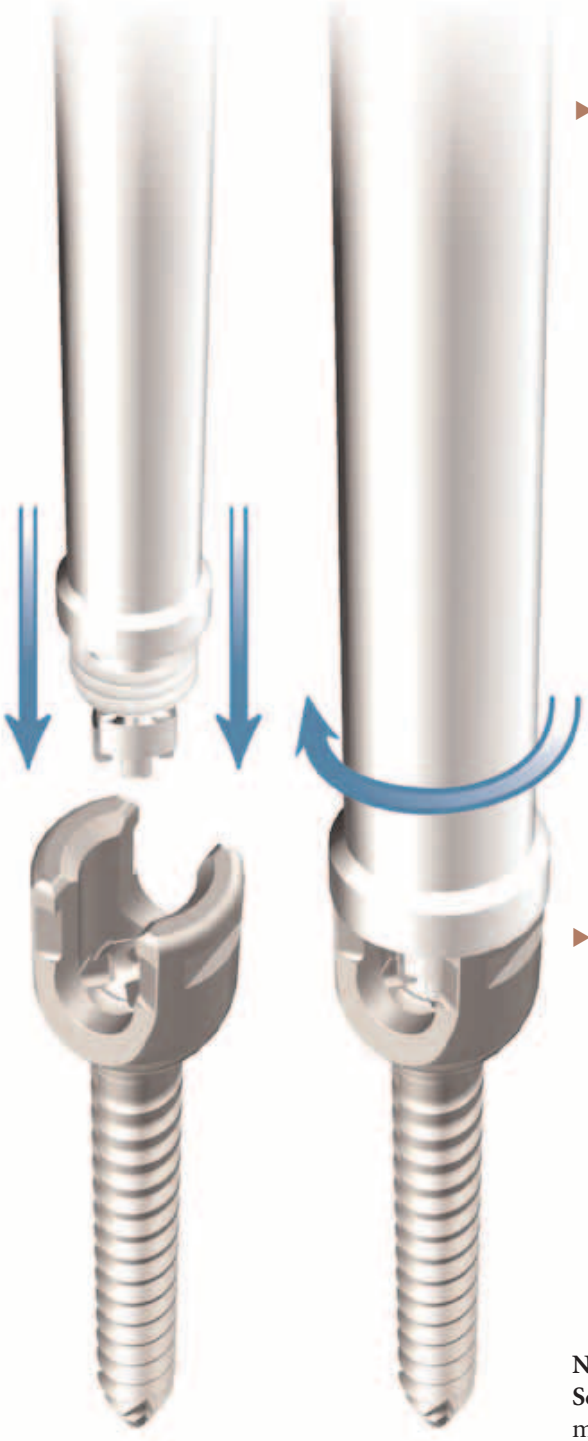
Note: Slide the **Tap Sleeve** proximal to the **Tap** shaft to engage the friction fit.

- Hold the **K-Wire** in position when removing the **Precision Tap**.

Screw Insertion

With the pedicle pathways prepared and proper screw length and diameter determined, the bone screw is prepared for insertion.

The **Xia® Precision Polyaxial Screwdriver** (**48231310**) provides a very rigid connection between the polyaxial bone screws and the screwdriver. The screwdriver can be attached to any of the cannulated modular handles using the quick release mechanism.



- Preload the **Screwdriver Protection Sleeve** (**48237009**) onto the **Xia® Precision Screwdriver**.

- Place a **Xia® Precision Bone Screw** on the distal end of the screwdriver and lock into place.

Note: The **Xia™ Polyaxial Screwdriver** (48041310) may be too short to use with some of the longer Luxor™ Retractor Blades.

Instrument Bar

Sharp 48230230
Blunt 48230231
K-Wire

48237001
Xia® Precision Square Awl

5.5mm 48230165
6.5mm 48230166
7.5mm 48230167
Xia® Precision Taps

48231315
Tap Sleeve

48231310
Xia® Precision Polyaxial Screwdriver

48237009
Screwdriver Protection Sleeve

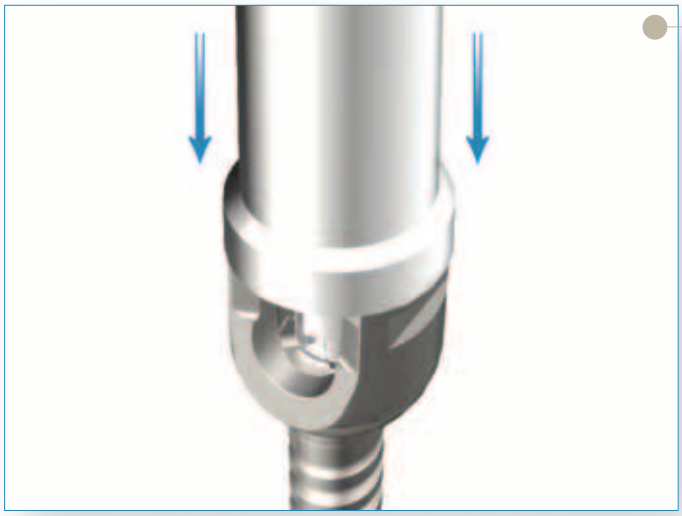


Figure 43

Note: With the **Xia® Precision Bone Screw** engaged with the **Precision Screwdriver**, the **Screwdriver Protection Sleeve** is slid over the proximal end of the screwhead to prevent the screwhead from contacting instruments during implantation.

Figure 44

- Place the **Xia® Precision Bone Screw** over the **K-Wire** and insert into the pedicle.

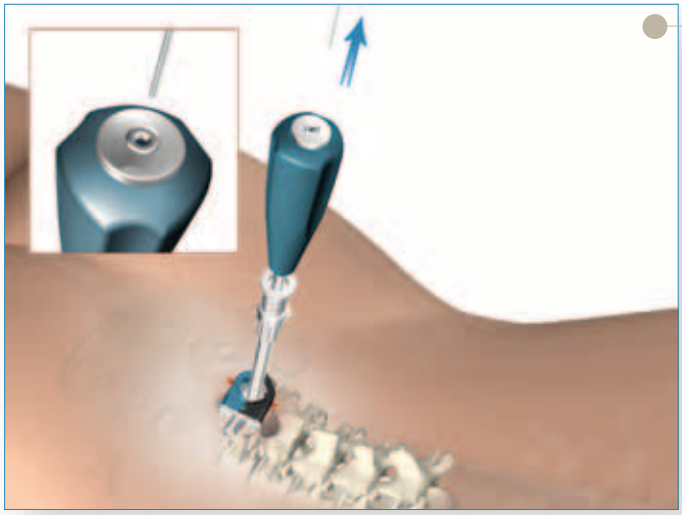


Figure 45

- After driving the screw assembly into the pedicle, remove the **K-Wire** to prevent it from advancing.
- Be certain that the screw assembly is not inserted too far. If the multi-axial head of the **Xia® Precision Bone Screw** is driven too forcefully against bone, it will lose its multi-axial capabilities making it difficult to connect the assemblies during subsequent steps.

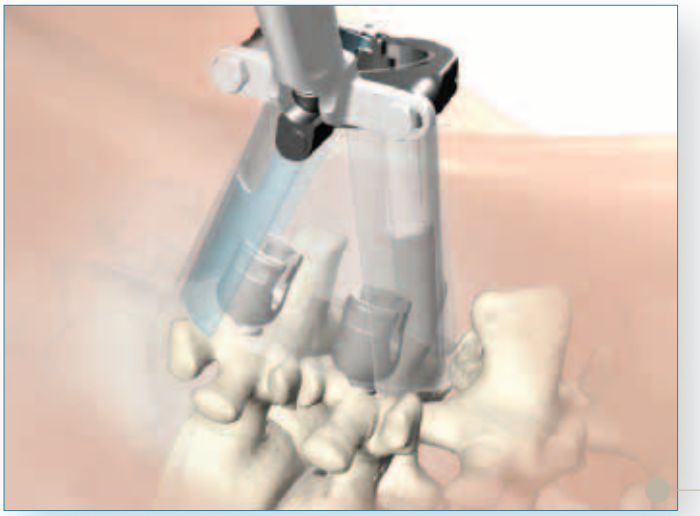


Figure 46

- Repeat the process for additional bone screws.
- After inserting additional bone screws, the head of the bone screws should be the same height.

Note: The polyaxial bone screws may lock upon insertion. Use the **Xia® Inserter** (**48047009**) to unlock the heads before introducing the rod.

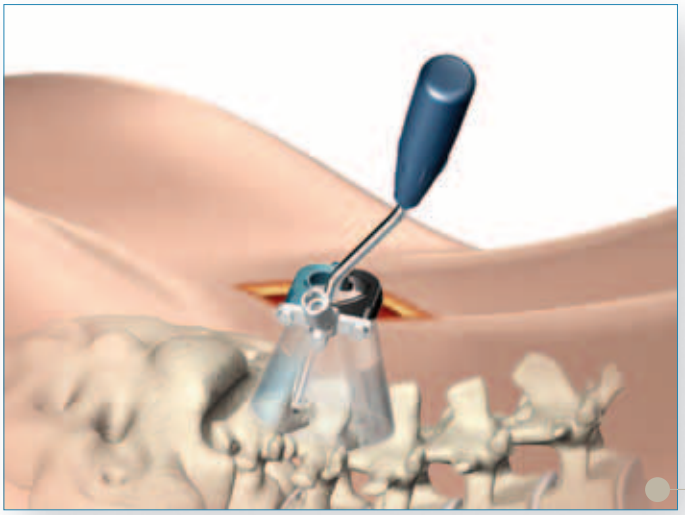


Figure 47

Screw Insertion: Non-Cannulated

- Use the **Bayoneted Awl** (**48250350**) to create a starting hole for the pedicle screw through the Luxor™ Retractor while not obscuring the surgeon's view.

Instrument Bar

48231310
Xia® Precision Polyaxial Screwdriver

48237009
Screwdriver Protection Sleeve

5.5mm 482315(35)-(50)
6.5mm 482316(30)-(55)
7.5mm 482317(30)-(55)
Xia® Precision Screw

Sharp 48230230
Blunt 48230231
K-Wire

48047009
Xia® Inserter

48250350
Bayoneted Awl

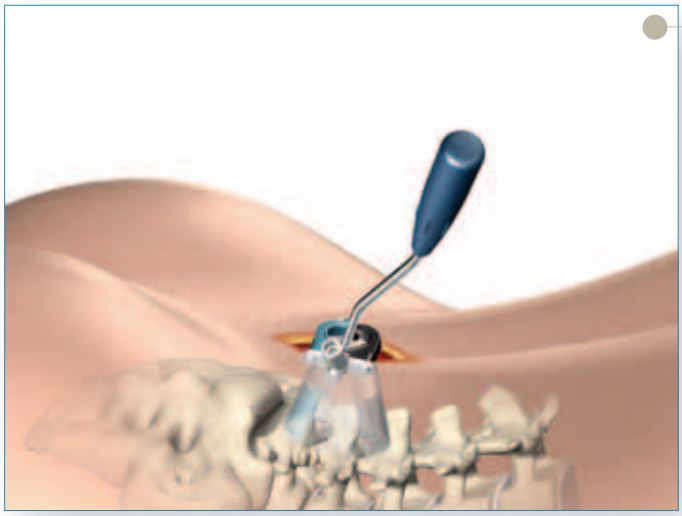


Figure 48

- Use the **Bayoneted Gear Shift (48250300)** to open up the pathway of the pedicle through the **Luxor™ Retractor** while not obscuring the surgeon's view.
- The **Gear Shift** should contact the bone at all times.
- The correct rotational insertion of the instrument will allow the **Gear Shift** to follow a path of least resistance without violating the pedicle walls.

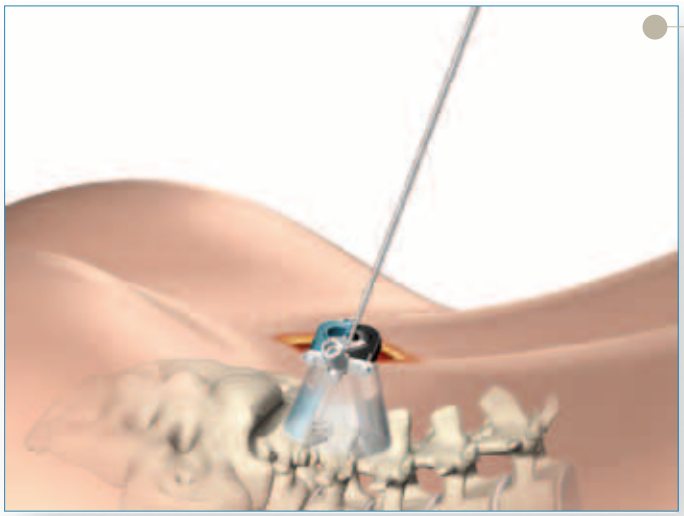


Figure 49

- Use the **Tapered Ball Probe (48250360)** to feel the wall of pedicle.

Note: The Tapered Ball Probe has markings at 30, 40, 50 and 60mm. Use imaging to determine the appropriate screw length.

Note: To ensure maximum exposure and maneuverability of the Luxor™ System, decortication can be facilitated when it is performed after pedicle probing and tapping and prior to screw placement.

See the Xia® Spinal System Operative Technique for pedicle screw insertion and package insert for indications, contraindications, warnings & precautions.

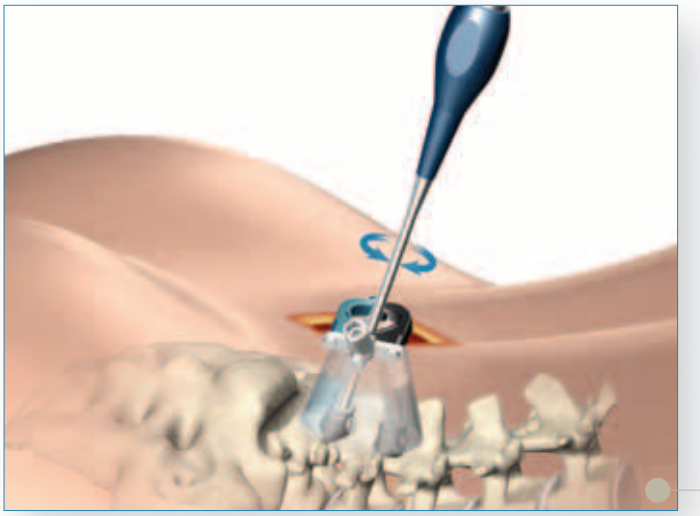


Figure 50

Rod Insertion

- Adjust the bone screw height using the **Xia Poly Adjustment Driver** (**48047033**).

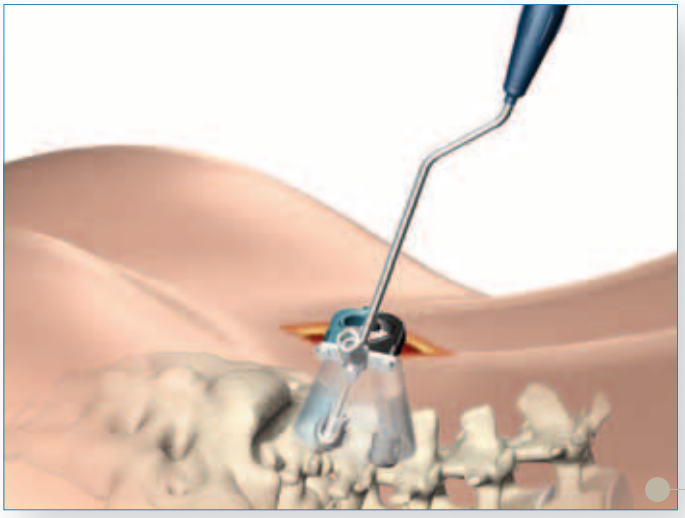


Figure 51

- Align the tulip heads of the bone screws using the **Screw Head Adjuster** (**48250310**) to facilitate rod insertion.

Instrument Bar

48250300
Bayoneted Gear Shift

48250360
Tapered Ball Probe

48047033
Xia® Poly Adjustment Driver

48250310
Screw Head Adjuster

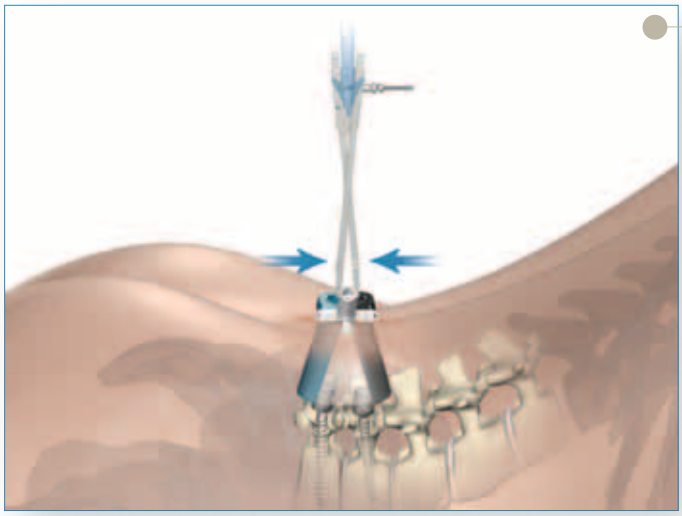


Figure 52

▶ Use the **Rod Calipers (48250320)** to determine the appropriate rod length.

1. Adjust the length of the **Rod Caliper** stems based on the corresponding **Blade Length**.
2. Collapse the **Rod Caliper** stems and insert into the Retractor.

Note: When using the Rod Caliper start with arms adjusted to longest blade length being used. When using the 120 mm blades the Rod Caliper arms should be fully extended.

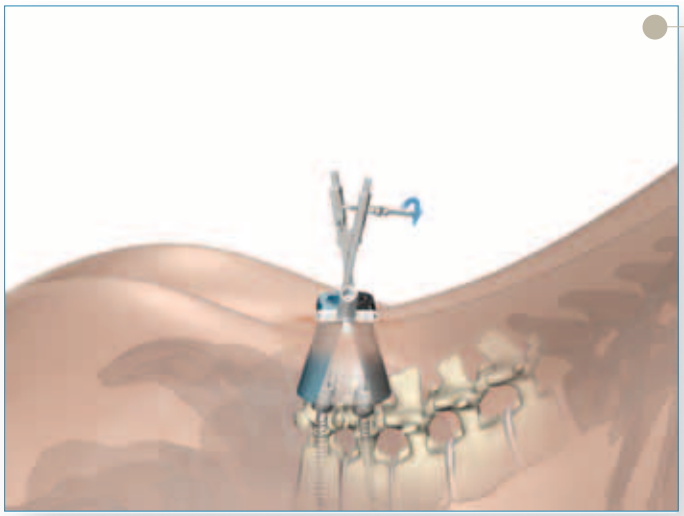


Figure 53

3. Dock the **Rod Caliper** stems onto the most superior and inferior bone screw heads.
4. Twist the nut on the **Rod Caliper** until slight pressure is felt once the nut contacts the Caliper stems.

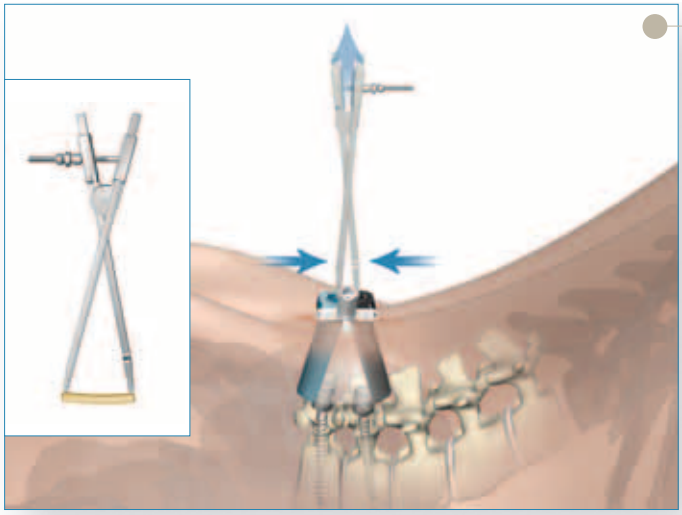


Figure 54

5. Remove the Rod Caliper from the Retractor. The stems will spring back to the position inside the Retractor.
6. Compare the distal span of the Rod Caliper stems with the rod sizes.

Note: Another way to determine rod lengths is by placing a rod of the estimated length in the Rod Holder and holding it over the surgical site. Use imaging to help determine the appropriate rod length.

Figure 55

▶ Perform rod bending with the **Xia™ French Bender** (**03807010**) to fit the desired spinal contours.

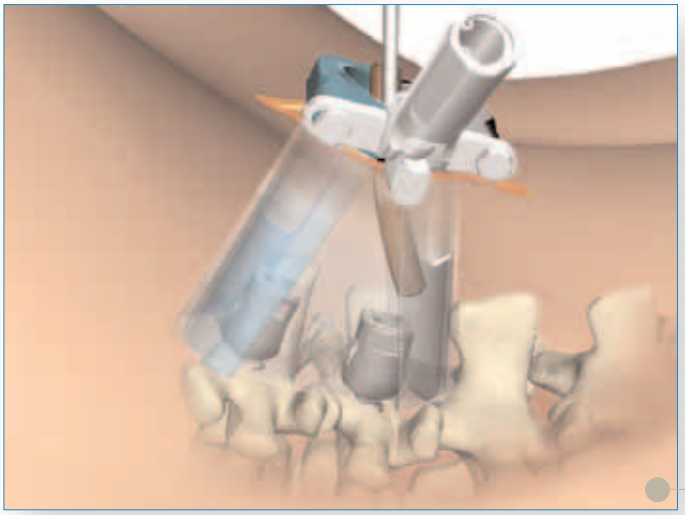


Figure 56

The **Rod Introducer** (**48250330**) is used through the Retractor to:

1. Transition the rod from a vertical to a horizontal orientation
2. Seat the rod into the screw head
3. Hold the rod in between screw heads
4. Adjust the rod between screw heads
5. Remove the rod during the surgical procedure

▶ Grasp the appropriate length rod in the middle using the Rod Introducer.

▶ Rotate the rod to a off-vertical orientation.

Instrument Bar

48250320
Rod Calipers

03807010
Xia® French Bender

48250330
Rod Introducer

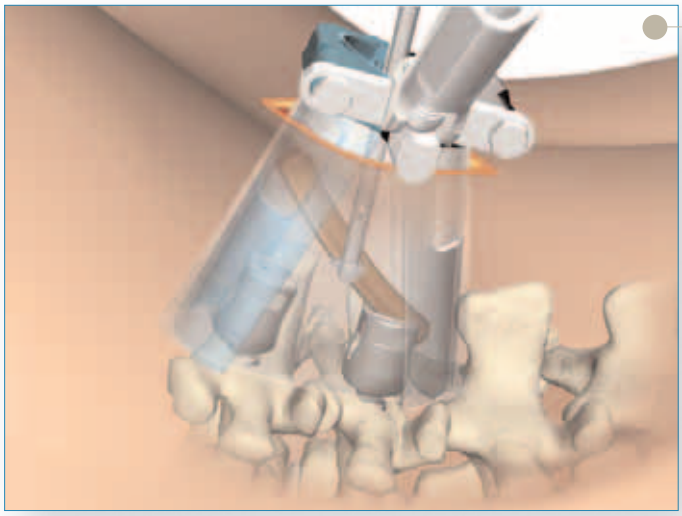


Figure 57

- Insert the rod through the Retractor Base.
- Place the distal section of the rod into the head of either the inferior or superior screw.

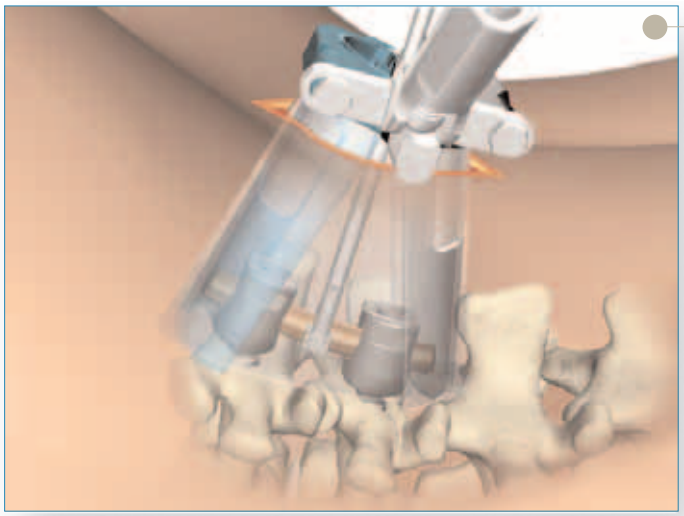


Figure 58

- Push down on the center of the rod to seat it into the remaining screw heads.
- Adjust the positioning of the rod such that it extends through the screws as seen on the lateral x-ray.

Note: It is recommended not to release the rod from the Rod Inserter until the Blockers are inserted into the screwheads.

Figure 59

Blocker Insertion

The **Inserter (48047009)** can help align the **Universal Tightener 5mm (03807008)** and the **Blocker (03756230)** through the Retractor.

The two engraved lines on the Universal Tightener denote the following:

1. When the lower line is aligned with the top of the Inserter, the Blocker is at the top of the implant.
2. When the upper line is aligned with the top of the Inserter, the Blocker is fully introduced into the implant.

Instrument Bar

6.0mm 482180(30)-(50)
6.0mm 482180(60)-(90)
Xia® Rad Rod

48047009
Xia® Inserter

03807008
Xia® Universal Tightener (5mm)

03756230
Xia® Blocker

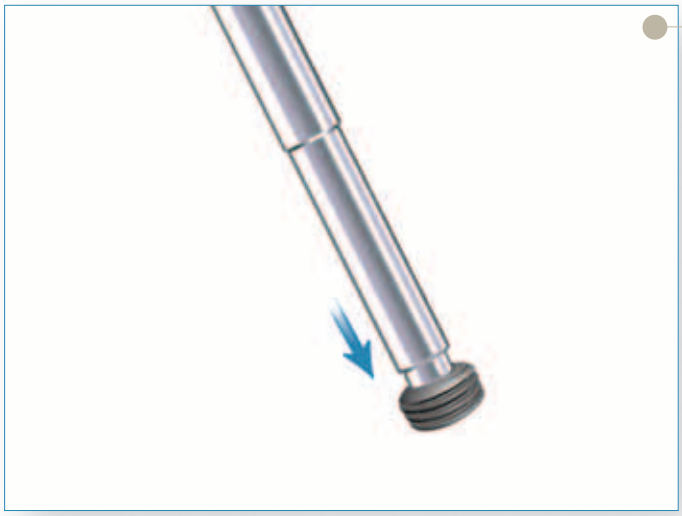


Figure 60

▶ Insert the **Universal Tightener** into the **Blocker.**

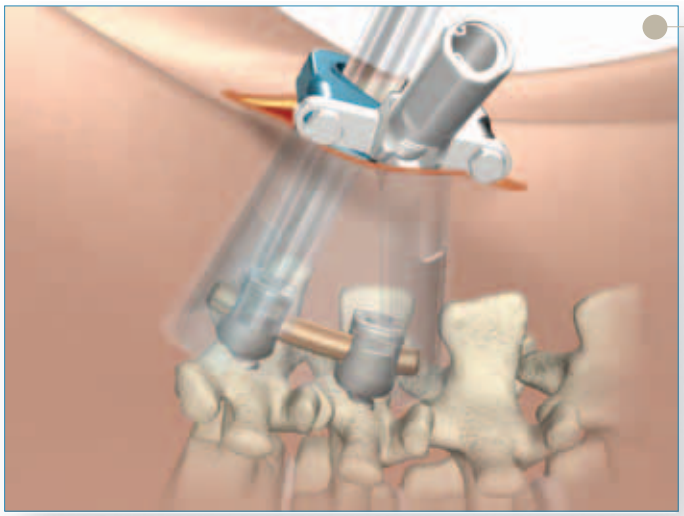


Figure 61

▶ Place the Inserter through the **Retractor** and dock it onto the screw head.

Note: Maintain the position of the rod in the screwheads using the Rod Inserter.

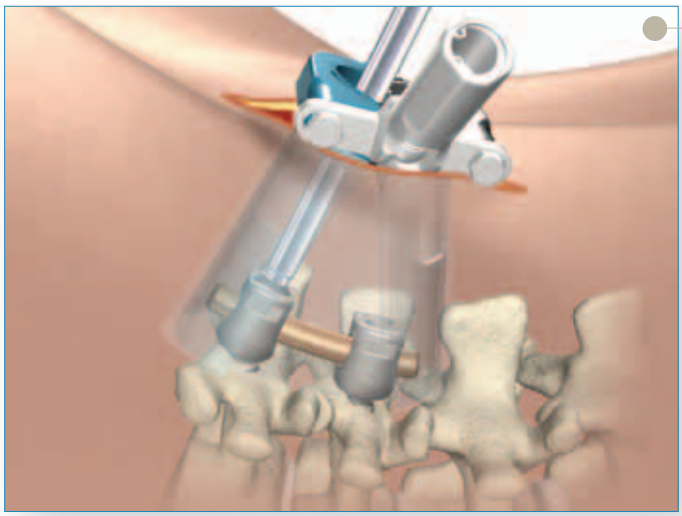


Figure 62

▶ Slide the **Universal Tightener** and **Blocker** through the Inserter and secure it in the tulip head of the screw.

▶ Rotate the **Blocker** clockwise to properly seat and temporarily tighten the **Blocker**.

Note: Do not perform final tightening of the **Blocker** with the Inserter in place, or it will not be possible to remove the Inserter.

▶ Repeat for other bone screws.

▶ Release the **Rod Inserter** from the rod once the Blockers are introduced.

Note: The Retractor may need to be repositioned for easier Blocker insertion by adjusting the Snake Arm or distal expansion.

Note: Use imaging and monitoring, as preferred, for added information during bone screw insertion.

Note: For easier blocker insertion, the Retractor may need to be repositioned by adjusting the Snake Arm or increasing the Retractor's distal blade expansion.

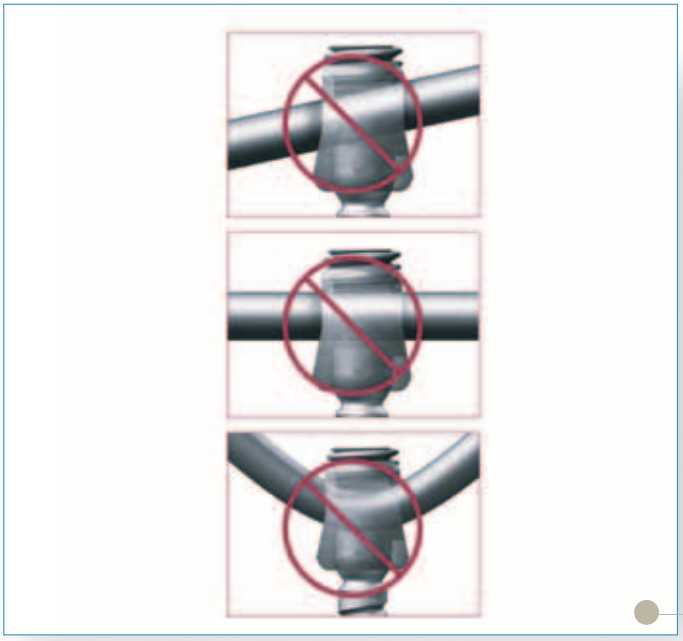


Figure 63

In the event the rod is forced down while tightening the Blocker, be sure that the Blocker is fully engaged into the bone screw head. This will help resist the high reactive forces generated by the final-tightening maneuvers.

Extra caution is advised when:

1. The rod is not horizontally placed into the screw head.
2. The rod is high in the screw head.
3. An acute convex or concave bend is contoured into the rod.

Instrument Bar

48047009
Xia® Inserter

03807008
Xia® Universal Tightener (5mm)

03756230
Xia® Blocker

03807019
Xia® Rod Pusher

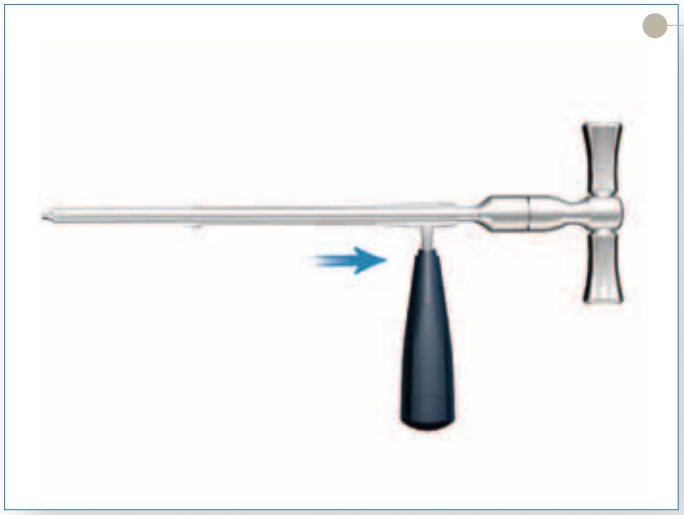


Figure 64

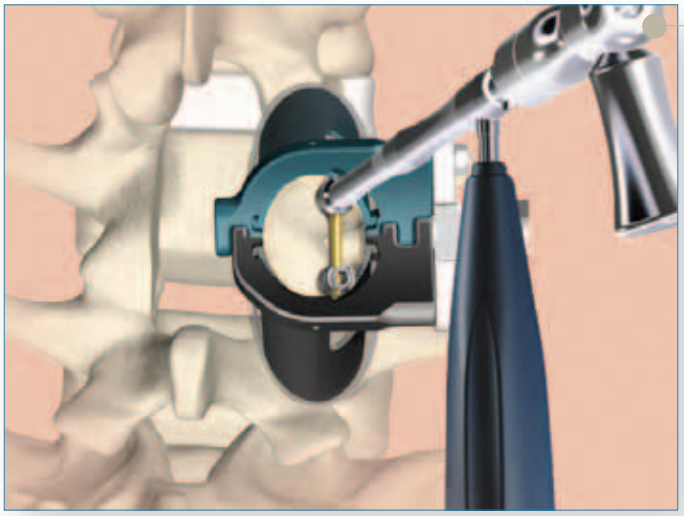


Figure 65

Construct Tightening

Once the correction procedures have been carried out and the spine is fixed in a satisfactory position, the final tightening of the Blocker is done by utilizing the **Anti-Torque Key** (**48027000**) and the **Torque Wrench** (**03807028**).

- Insert the **Torque Wrench** through the **Anti-Torque Key.**
- Mate the top of **Anti-Torque Key** with the bottom of the handle of the **Torque Wrench**.
- Insert the final tightening assembly through the **Retractor**.
- Visualize the distal end of the **Torque Wrench** entering the **Blocker**.
- Dock the **Anti-Torque Key** on the **Screw**.
- Line up the two arrows on the **Torque Wrench** to achieve the optimum torque of 12Nm for final tightening of the implants.

Note: The Anti-Torque Key must be used for final tightening. The Anti-Torque performs two important functions:

1. It allows the Torque Wrench to align with the axis of the tightening axis.
2. It allows one to maximize the torque needed to lock the implant assembly.

Note: If the Anti-Torque Key cannot be easily removed from the implant head, the rod may not be fully seated.

- Apply bone graft to the fusion site and close in the usual manner.

Note: For additional information, please refer to the Xia® Surgical Technique.

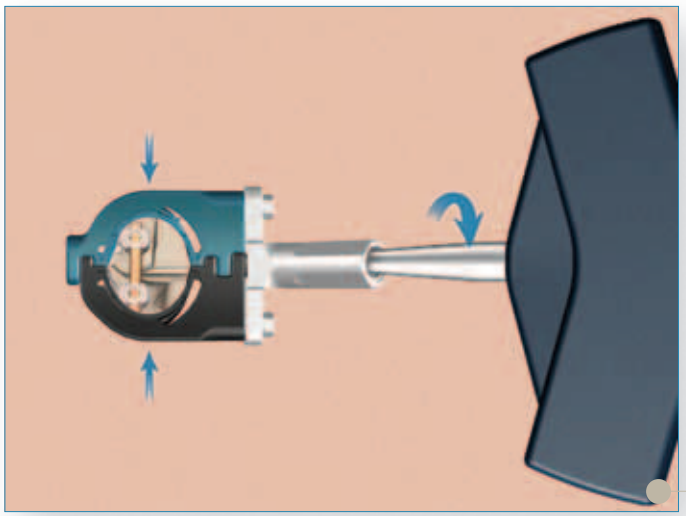


Figure 66

Closure

- Examine the site for bleeding.
- Close the **Retractor Base** with the **Driver** before withdrawing it from the incision. The muscle and fascia close as the retractor is withdrawn through the dilated tissues.
- If accessible, close the fascia with one or two interrupted sutures. The subcutaneous tissue is closed in an inverted manner. A subcuticular closure is performed. Cover the skin edge with clear waterproof dressing.

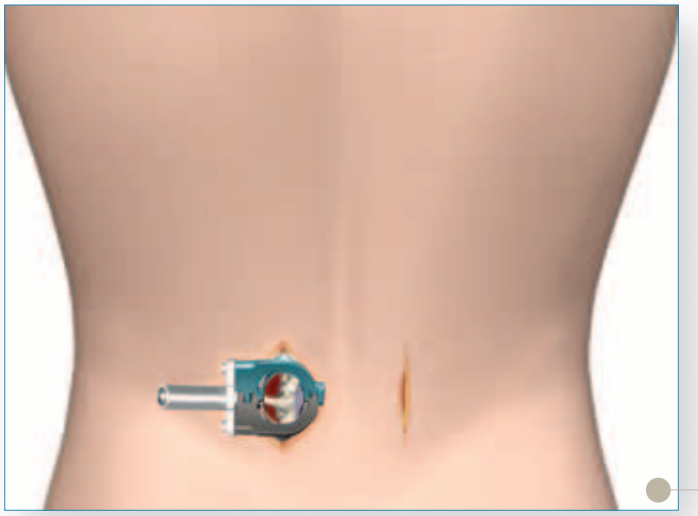


Figure 67

Contralateral Side

Move to the opposite side of the patient and repeat the steps of the technique on the contralateral side.

It is recommended that a visible inspection of the surgical site be performed followed by irrigation and suction post procedure to insure that no existing implantable materials are left in-situ.

Instrument Bar

03807028
Xia® Torque Wrench

48027000
Anti-Torque Key

Catalog #	Description
Instruments	
48250000	Luxor™ Retractor Tray
48250230	Snake Arm
48250240	Arm Post
48250010	Guide Pin
48250011	Cobb Style Initial Dilator
48250017	Kelly Retractors
48250018	Blunt Dissector
48250020	Retractor Base
48250040	Set of Retractor Blades 40mm
48250050	Set of Retractor Blades 50mm
48250060	Set of Retractor Blades 60mm
48250070	Set of Retractor Blades 70mm
48250080	Set of Retractor Blades 80mm
48250090	Set of Retractor Blades 90mm
48250105	Set of Retractor Blades 105mm
48250120	Set of Retractor Blades 120mm
48251040	Set of Silicon Sleeves 40mm
48251050	Set of Silicon Sleeves 50mm
48251060	Set of Silicon Sleeves 60mm
48251070	Set of Silicon Sleeves 70mm
48251080	Set of Silicon Sleeves 80mm
48251090	Set of Silicon Sleeves 90mm
48251105	Set of Silicon Sleeves 105mm
48251120	Set of Silicon Sleeves 120mm

Catalog #	Description

Instruments

48250210	Lighting Component

48250215	Universal Light Cable

233-050-071	Stryker / ACMI / Zimmer Lightsource Adapter
233-050-073	Storz Lightsource Adapter
233-050-072	Olympus Lightsource Adapter
233-050-074	Wolf / Dyonics Lightsource Adapter

48250200	Driver

48240005	Reliance LITe Decompression Tray

48242240	Kerrison Bayoneted 2mm, 40 degree
48242290	Kerrison Bayoneted 2mm, 90 degree
48242340	Kerrison Bayoneted 3mm, 40 degree
48242390	Kerrison Bayoneted 3mm, 90 degree
48242440	Kerrison Bayoneted 4mm, 40 degree
48242490	Kerrison Bayoneted 4mm, 90 degree
48242540	Kerrison Bayoneted 5mm, 40 degree
48242590	Kerrison Bayoneted 5mm, 90 degree

48242200	Kerrison Bayoneted Upbiting (curved up at tip), 2mm
48242400	Kerrison Bayoneted Upbiting (curved up at tip), 4mm

	Catalog #	Description
		Instruments
	48243045 **48243090**	Woodson Probe Bayoneted 45 degree Woodson Probe Bayoneted 90 degree
	48243000 **48243001**	Ball Probe Bayoneted 110 degree, Straight, Long Ball Probe Bayoneted 110 degree, Straight, Short
	48244102 **48244202** **48244104** **48244204**	Penfield Bayoneted, Pull #2 Penfield Bayoneted, Push #2 Penfield Bayoneted, Pull #4 Penfield Bayoneted, Push #4
	48241103	Nerve Hook Bayoneted, 90 degree, Blunt Tip
	48241201 **48241202**	Nerve Root Retractor Nerve Root Retractor, Wide
	48245001 **48245002**	Suction Tip with Bend Suction Tip with Bend, with Lip
	48245010	Micro Scissor (Single Action)
	20-1490KI	Bi Polar Forceps (US Connection), Angled
	E1457	Colorado MircoNeedle 7 inch Sleeve, 2 inch 45 degree bend
	48247001	Sypert Rongeur

Catalog #	Description
Instruments	
48250001	Luxor™ Fixation Instruments Tray
48250300	Bayoneted Gear Shift
48250310	Screw Head Adjuster
48250320	Rod Calipers
48250330	Rod Introducer
48250350	Bayoneted Awl
48250360	Tapered Ball Probe
48047033	Xia® Poly Adjustment Driver
03807008	Xia® Universal Tightener (5mm)
48047009	Xia® Inserter
03807028	Xia® Torque Wrench
03807010	Xia® French Bender
48027000	Anti-Torque Key
03807019	Xia® Rod Pusher

Removal or Revision Procedures

The spinal implants are temporary internal fixation devices designed to stabilize the operative site during the normal healing process. After healing occurs, these devices usually serve no functional purpose and can be removed. Removal may also be recommended in other cases, such as:

- Corrosion with a painful reaction
- Migration of the implant, with subsequent pain and/or neurological, articular or soft tissue lesions
- Pain or abnormal sensations due to the presence of the implants
- Infection or inflammatory reactions
- Reduction in bone density due to the different distribution of mechanical and physiological stresses and strains
- Bone growth restraint due to the presence of the implants (in pediatric use)
- Failure or mobilization of the implant

Standard ancillaries provided by Stryker Spine can be used to remove the implants. Any decision by a physician to remove the internal fixation device should take into consideration such factors as the risk to the patient of the additional surgical procedure as well as the difficulty of removal. Removal of an unloosened spinal screw may require the use of special instruments to disrupt the interface at the implant surface. This technique may require practice in the laboratory before being attempted clinically. Implant removal should be followed by adequate postoperative management to avoid fracture or re-fracture. Removal of the implant after fracture healing is recommended. Metallic implants can losen, bend, fracture, corrode, migrate, cause pain or stress shield bone.

Notes

Notes

stryker®

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A surgeon must always rely on his or her own professional clinical judgment when deciding to use which products and/or techniques on individual patients. Stryker is not dispensing medical advice and recommends that surgeons be trained in knee implant surgeries before performing any knee surgeries.

Surgeon must always rely on their own clinical judgment when deciding which treatment and products to use with their patients.

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